

MAR - 1 2004



510(k) Summary
PerioGlas - Bioglass Bone Graft Particulate

02/03/04

1. Submitter Information:

Name: NovaBone Products, LLC
Address: 13709 Progress Boulevard, #33
Alachua, FL 32615
Telephone: (386) 462-7660
Facsimile: (386) 418-1636
Contact: David M. Gaisser

2. Name of Device:

Trade Name: PerioGlas – Bioglass Bone Graft Particulate
Common Name: Osteoconductive Bone Void Filler
Synthetic Resorbable Bone Graft Material
Classification Name: Endosseous Implant for Bone Filling and/or Augmentation

3. Legally Marketed Predicate Device:

Predicate: PerioGlas – Synthetic Bone Graft Particulate
[K992416, K962492, K930115]
(Also named as NovaBone per Special 510(k) K000149)

4. Device Description

PerioGlas is a synthetic absorbable osteoconductive bone graft substitute composed of a calcium phospho-silicate bioactive glass, Bioglass[®]. The device is in a particulate form of a size range 90-710 μ m. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects. It is supplied sterile, packaged either in a Tyvek-sealed PET-G cup or in a filled syringe within a second sterile barrier package. The device packages are protected by an outer shrink-wrapped cardboard box. At time of use, the device is mixed with sterile water, saline, the patient's own blood or marrow, or with autogenous or allograft bone to form a wet sandy paste that is applied to the defect.

5. Intended Use

PerioGlas – Bioglass Bone Graft Particulate is indicated to be packed into bony voids or gaps to fill and/or augment oral, dental intraosseous, and craniofacial defects. These defects may include: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge

maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. PerioGlas may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either as a bone graft extender.

6. Technological Characteristics

The technological characteristics of the proposed device and the unmodified PerioGlas device are identical. The *in vivo* and clinical performance of this device was previously evaluated in K992416. Packaging and labeling verification testing resulting from FMEA risk analysis was completed following design control.

7. Complications

The modifications made to the PerioGlas device do not result in a change in complications associated with the use of the device. Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery. Complications specific to oral/dental use are those as may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation

8. Conclusion

The modifications made to the PerioGlas device do not result in a change in technological characteristics of the device. PerioGlas devices continue to be safe and effective as non-structural osteoconductive bone void fillers for oral and cranio-/maxillofacial defects following modifications to include filled syringe packaging and gamma irradiation sterilization.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David M. Gaisser
Director, Operation
NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K040278
Trade/Device Name: PerioGlas- Bone Graft Particulate
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: February 3, 2004
Received: February 1, 2004

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph., D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K040278

Confidential

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K040278

Device Name: PerioGlas - Bioglass Bone Graft Particulate

Indications For Use:

The intended use of PerioGlas is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and craniofacial defects. It is used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone) or may be mixed with either (typically 1:1 ratio v/v) as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge Augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/ placement)
- Sinus lifts
- Cystic cavities
- Cranio-facial augmentation

For larger defects, a mixture of PerioGlas[®] with an equal volume of allograft or autograft bone and bone marrow may improve new bone formation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040278

Prescription Use ☒

OR
(Per 21 CFR 801.109)

Over-The-Counter Use ☐